K092822

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	VivaRay, Inc.
TRADE NAME:	CAPRI™ Applicator
COMMON NAME:	Brachytherapy Applicator
CLASSIFICATION NAME:	Remote Controlled Radionuclide Applicator System, 21 CFR, 892.5700
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	JAQ
PREDICATE DEVICES:	BioLucent's Applicator (K061241) Nucletron's Miami Applicator (K953946)

NOV - 3 2009

Substantially Equivalent To:
The CAPRI Applicator is substantially equivalent in intended use, principal of operation and technological characteristics to the BioLucent Applicator (K061241) and the Nucletron Miami Applicator (K953946).

Description of the Device Subject to Premarket Notification:

The CAPRI Applicator is a specialized applicator that is temporarily inserted into the vagina or rectum to facilitate the application of radiation to the target site in the treatment of carcinoma.

The CAPRI Applicator is provided sterile for single use and is disposable.

Indication for Use:

The CAPRI Applicator is intended for use during brachytherapy procedures. The multiple lumens of the CAPRI Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

Technical Characteristics:

The CAPRI Applicator has similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed for the CAPRI Applicator to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the CAPRI Applicator is determined by VivaRay, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. George Hermann
President
VivaRay, Inc.
3264 Alpine Road
PORTOLA VALLEY CA 94028

NOV - 3 2009

Re: K092822
Trade/Device Name: CAPRI™ Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 10, 2009
Received: September 14, 2009

Dear Mr. Herman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092822

Device Name: **CAPRI™ Applicator**

Indications for Use:

The CAPRI™ Applicator is intended for use during brachytherapy procedures. The multiple lumens of the CAPRI Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use __X__ (Per 21 CFR 801.109)

Over-The-Counter Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092822